

REMARKS

Claims 64 and 78 are currently amended. Claim 71 is canceled. It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I: Rejection of Claims 64-76 and 74-94 under 35 U.S.C. 101

Independent Claims 64 and 78 are currently amended. Reconsideration is urged.

II: Rejection of Claims 64-95 under 35 U.S.C 112 (1st paragraph)

Claims 64-95 stand rejected for two reasons. First the Examiner contends that "an amino acid sequence" refers to fragments. Second the Examiner objects to the term comprising. Applicants have amended the independent claims to refer to "the" amino acid sequence of SEQ ID No: 10. Reconsideration is urged.

With respect to the rejection relating to "comprising", Applicants traverse this rejection.

Section 112, first paragraph provides that:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same....

The written description requirement of 35 U.S.C. § 112, first paragraph, is fulfilled when the patent specification describes the claimed invention in sufficient detail such that the claim limitations are described so that one of skill in the art would recognize that the applicants had invented the subject matter. See *Vas-Cath, Inc. v. Mahurkar*, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); *In re Herschler*, 591 F.2d 693, 700 (C.C.P.A. 1979). The written description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See *In re Marzocchi*, 169 U.S.P.Q. 367 (CCPA 1971).

The written description requirement can be met by showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with known or disclosed correlation between function and structure, or some combination of such characteristics. See, e.g., *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398, 1404 (Fed. Cir. 1997); *Enzo Biochem v. Gen-Probe Inc.*, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002). A description of a claimed genus may be achieved by recitation of a representative number of species falling within the scope of the genus or by a recitation of structural features common to the members of the genus which constitute a substantial portion of the genus. See *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d at 1569.

The claimed invention is drawn to isolated laccase of SEQ ID NO: 10, including the following mutations:

- (a) H93E;
- (b) H95E;
- (c) D106A, D106F, D106I, D106L, D106P, D106V, D106W, or D106Y;
- (d) A108F, A108I, A108L, A108P, A108V, A108W, or A108Y;
- (e) N109A, N109D, N109F, N109I, N109L, N109P, N109Q, N109V, N109W, or N109Y;
- (f) T428A, T428F, T428I, T428L, T428P, T428V, T428W, or T428Y;
- (g) L500F, L500I, L500W, or L500Y;
- (h) A506E;
- (i) S510A, S510F, S510I, S510L, S510P, S510V, S510W, or S510Y;
- (j) G511F, G511I, G511L, G511P, G511V, G511W, or G511Y; or
- (k) G514A, G514F, G514I, G514L, G514P, G514V, G514W, or G514Y;

wherein the isolated laccase having laccase activity. Thus, the claims require that (1) the isolated laccase is the laccase of SEQ ID NO: 10; (2) the isolated laccase includes at least one specific mutation at the position specified above; and (3) the isolated laccase has laccase activity. Because of these claim requirements, the claims provide structural limitations on the isolated laccase(s) of the present invention.

Moreover, the specification specifically describes a number of other positions and mutations, which can be combined with the claimed substitution. For example, the variants may further comprise the mutations shown on the bottom of page 10 where it

refers to SEQ ID NO: 10, or on the bottom of page 11 where it refers to SEQ ID NO:10, or on page 12 referring to SEQ ID NO: 10. For example, one modification suitable for use in accordance with the present disclosure is M433E which was clearly described, but is no longer in the independent claims.

Thus, the Examiner is incorrect that the specification fails to describe any other species. Contrary to the Examiner's allegations, the specification discloses numerous various lacasse of the present disclosure and evidences that Applicants possessed these species. These species are a representative number of species within the scope of the genus and therefore Applicants' disclosure evidences that Applicants were in possession of the claimed genus of isolated laccase at the time the application was filed.

Moreover, the level of skill in the art of enzyme variants is very high. Indeed, there are numerous U.S. patents on laccase variants comprising a mutation at one or more positions. Examples of recently-issued U.S. patents are U.S. Patent Nos. 6,140,092, 5,998,353. It would be routine for one of ordinary skill in the art to combine the substitution recited in claims 64 and 78 of the present application with any of the mutations described in the prior art. Applicants note that the each initial claim of both of the patents uses the transition term "comprising" or "comprises".

In sum, Applicants' specification provides (1) a precise definition by structure of the genus of isolated lacasse(s) sufficient to distinguish it from other isolated laccases and (2) a description of numerous representative members of the genus, in sufficient detail so that one of skill in the art would recognize that Applicants had invented the claimed subject matter. Accordingly, Applicants respectfully submit that the rejection of claims 64 and 78 as failing to comply with the written description requirement is improper and should be reversed.

III: The Rejection of Claims 64-95 Under 35 U.S.C. 112, 1st paragraph (enablement).

Claims 64-95 are rejected under 35 U.S.C. 112, 1st paragraph, because while the specification is enabled for variants of laccase having the amino acid sequence of SEQ ID NO: 10 and the identified mutations having laccase activity, it does not reasonably provide enablement for variants having any structure.

Each independent claim has been amended to change "an" to "the". The Examiner has indicated on the record that the claims are enabled for variants of a lacasse "having the amino acid sequence of SEQ ID NO:10". . . See page 7 of the

Official Action. Accordingly Applicants have fully responded to this rejection by way of amendment. Reconsideration is urged.

IV: Rejection of Claims as Anticipated

The Examiner has indicated that the claims are anticipated under several references. The Applicants have currently amended each independent claim, and thus have fully responded to each of the Examiner's rejections. Reconsideration of each independent claim, as amended, is urged.

V. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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